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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,192	12/31/2003	Pei Kan	KANP3002/REF	5546

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EXAMINER	
FARZANEH, SHAHRZAD	

ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,192	KAN ET AL.	
	Examiner	Art Unit	
	SHAHRZAD FARZANEH	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of temperature sensitive polymer, physiological acceptable oil phase carrier, and bioactive substance in the reply filed on 10/19/2007 is acknowledged. The traversal is on the ground(s) that no reasons are set forth in the species election requirement as to why the species are patentably distinct. This is found persuasive because there is no undue search burden on the Office for the claimed species, and as such, the species election requirement is withdrawn. Claims 1-10 are pending in the application, and are under examination in this Action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5543158 to Gref et al. and in view of US Patent No. 6592899 to Fowers et al.

Gref et al. teaches block polymer of polyesters of PLGA and PEG (triblock) in an injectable form to be delivered along with an imaging substance, such as Dextran (see column 4 lines 45-50 and column 5 lines 14-15). It has been reported that the block copolymer of polylactic acid and poly(ethylene glycol) can be used for the injectable controlled administration of biologically active materials. However, it has now been discovered that the copolymer of lactic acid and glycolic acid, as well as other polymers such as polyanhydrides, polyhydroxybutyric

acid, polyorthoesters other than the homopolymer of lactic acid, polysiloxanes, polycaprolactone, or copolymers prepared from the monomers of these polymers can also be used to prepare injectable nanoparticles for the delivery of biologically active materials. The variety of materials that can be used to prepare the injectable particles significantly increases the diversity of release rate and profile of release that can be accomplished in vivo (see column 7, lines 13-27). Biodegradable polyanhydrides are also taught by Gref et al., as bioactive materials in the injectable delivery system of the present invention.(see lines 28-30). Gref, et al. further teaches a biologically active molecule, such as an antibody or antibody fragment can be covalently bound to the triblock polymer (see column 11, lines 37-40). Furthermore, Gref, et al. teaches an emulsion, formed by adding distilled water to the solution of the block polymer, creating an oil and water emulsion, as in Example 4 of the present invention (see column 13, lines 35-37 and column 14, lines 33-36).

4. Gref, et al. does not teach; however, the provision of solubilization of hydrophobic drugs and the use of a fatty acid ester as the oil phase carrier of the formulation. The teaching of Fowers, et al, does teach a biodegradable polymeric composition capable of solubilizing a drug, particularly a hydrophobic drug, into a hydrophilic environment and may be used in the preparation of pharmaceutically effective formulation of such drugs (see column 3, lines 27-30). The block polymers have 50.1% to 65% by weight content in the polymer block (see column 3, lines 45-51). Fowers, et al. goes on to teach that biodegradable polyesters, for example, the fatty acid ester of butyric acid can be used as an oil phase carrier in the formulation (see column 4 lines 64-66, and column 6, line 2). Fowers, et al. also teaches a triblock polymer embodiment, as shown in Example 1 of the present invention (see column 11, lines 23-42).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAHRZAD FARZANEH whose telephone number is (571)270-1557. The examiner can normally be reached on Weekly 7:30-5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SF

/Ardin H Marschel/

Supervisory Patent Examiner, Art Unit 1614